

# **EXHIBIT 1**

## **Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection**

The purpose of these guidelines is to provide guidance to health services staff about screening and testing offenders to determine whether they have a chronic hepatitis C virus (HCV) infection; evaluating HCV infected offenders for treatment with antiviral agents; and monitoring the condition of HCV infected offenders during and after treatment. These guidelines will be updated periodically in accordance with treatment recommendations by nationally recognized authorities, such as the American Association for the Study of Liver Disease (AASLD), are revised.

### **1. Intake Screening for Risk of HCV Infection**

At intake, DOC staff will:

- a. Explain the HCV risk factors to offenders and recommend that offenders request blood testing if they have any of the risk factors;
- b. Provide education information on transmission, development and potential impact of chronic HCV infection, what HCV testing involves, and how chronic HCV infection is managed and treated; and
- c. Explain procedures for requesting HCV blood test.

### **2. Blood Testing for HCV**

Blood testing for HCV includes a screening blood test for the HCV antibody and, if that test is positive, a confirmatory test to determine whether there is active infection (HCV RNA).

- a. All HCV blood testing is voluntary.
- b. HCV blood tests may be requested by an offender or ordered by a practitioner.
- c. Offenders who request HCV blood testing will not be charged a co-pay or be required to disclose the presence of any risk factor(s).

### **3. Evaluating HCV Infected Offenders**

Offenders determined to have an active infection (HCV RNA positive) will have an initial evaluation and periodic evaluations to determine what treatment, if any, is required and when.

#### **a. Initial Evaluation**

Practitioners at each facility will conduct an initial evaluation that includes:

- 1) targeted history and physical exam;
- 2) laboratory testing, such as liver profile, complete blood count (CBC), and HCV genotype, and any other tests the practitioner determines are indicated;

- 3) immunization for hepatitis A and B or testing for immunity for these diseases, if indicated;
  - 4) explanation of the process for periodic evaluation and criteria for determining treatment eligibility; and
  - 5) providing the offender with written instructions about how frequently the offender should arrange for periodic evaluations.
- b. Periodic Evaluation of Chronic Infection
- Because chronic HCV infection can cause liver damage, offenders identified as HCV RNA positive should be evaluated periodically to monitor the progression of the disease.
- 1) Offenders must arrange for periodic evaluations of their condition in accordance with the written instructions provided by the practitioner who completed the initial evaluation; must follow procedures at the facility where they reside to request a periodic evaluation; and will not be charged a co-payment for periodic evaluations.
  - 2) Practitioners at the facilities will conduct the periodic evaluations, which will generally consist of:
    - a) an interim targeted history and physical exam;
    - b) lab testing, CBC, and liver profile;
    - c) other testing as clinically indicated, including blood test panel to determine liver fibrosis (e.g. Fibrotest or Fibrosure); basic metabolic panel (BMP); abdominal ultrasound or alternative imaging studies (e.g. Fibroscan); or liver biopsy
- c. Practitioners and/or facility staff will complete a Hepatitis C Case Report after the initial evaluation and an updated Hepatitis C Case Report after each periodic evaluation and send the report and results of all related lab tests to the DOC medical director.

#### 4. Approving Anti-viral Treatment

Based on the updated Hepatitis C Case Reports and additional clinical information, the DOC Medical Director or designee may authorize patient-specific antiviral treatment.

- a. Only FDA approved medications will be used for HCV treatment.
- b. Generally, the DOC Medical Director will approve anti-viral treatment for offenders with advanced fibrosis (stage 3-4); or for offenders with mild fibrosis (stage 2) who have concurrent hepatitis B or HIV infection or end organ damage caused by HCV infection.
- c. Treatment regimens approved will be consistent with current treatment recommendations established by a nationally recognized authority, such as the American Association for the Study of Liver Disease (AASLD), and patient-specific factors, such as genotype, HCV viral load, disease stage, co-existing medical

conditions, medication interactions (real or possible), time remaining on term of imprisonment, and compliance with previous medical treatment.

- d. Treatment will not be approved for those with terminal conditions or known allergy or previous serious adverse reaction to one or more of the treatment medications.
- e. Treatment may be deferred if an offender has a recent history of non-adherence to medical monitoring or medication treatment, recent documented illicit drug or alcohol use while in the prison system, and unstable medical condition that may impact the continuity of treatment (such as a planned surgery) or may impact the outcome of anti-viral treatment.
- f. HCV anti-viral treatment will be administered as directly observed therapy by nursing staff.

## **5. Monitoring During and After Anti-viral Treatment**

Practitioners at the facility will monitor to ensure that offenders who are receiving anti-viral treatment are complying with their treatment regimens and to determine the effectiveness of the treatment.

- a. Practitioners will obtain lab tests prior to and during treatment weeks, as established by the lab monitoring guidelines.
- b. Practitioners will report to the Medical Director all information related to the effectiveness of antiviral treatment, including such examples as:
  - 1) the offender is not complying with the treatment regimen, clinical monitoring or lab testing;
  - 2) the offender has a significant adverse or allergic reaction to a medication that cannot be managed medically;
  - 3) laboratory tests reveal evidence of treatment failure based on continued presence of HCV virus in the blood; or
  - 4) evidence of illicit drug or alcohol use during treatment.

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